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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,687	03/30/2001	Katsuhiko Mikoshiba	081356-0162	9222

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FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/821,687

Applicant(s)

MIKOSHIBA ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 Jan. 2003 and 30 Oct. 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,9-20 and 24-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,6,8,21 and 23 is/are rejected.
- 7) ☒ Claim(s) 3,5,7 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-36 are pending in the present application. Claims 3-8 and 21-23 are pending in the present application.

Election/Restrictions

Applicant's election with traverse of Group II and SEQ ID NO:3 in Paper Nos. 11 and 13 is acknowledged. In applicant's response filed 14 January 2003, Applicant indicated that Group II was elected without traverse. However, Paper No. 13 provides arguments in traverse of the restriction requirement, which are addressed herein. The traversal is on the ground that the examiner has failed to demonstrate that a serious burden exists to examine SEQ ID Nos:1-4. This is not found persuasive because sequences encoding different proteins and nucleic acids are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide or amino acid sequence is presumed to represent an independent and distinct invention. A search burden does indeed exist due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application. However, as a courtesy to Applicant and to expedite prosecution of the present Application, the nucleic acid sequence encoded by SEQ ID NO:4 will also be examined.

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The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 9-20 and 24-36 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Accordingly, claims 3-8 and 21-23 are pending in the present application.

Specification

The disclosure is objected to because of the following informalities: Figure 2 discloses sequences without reference to the appropriate sequence identifier. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. 131 and 132.

A complete reply to this office action requires that Applicant correct this defect. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claims 3, 5, 7 and 22 are objected to as containing non-elected subject matter. Appropriate correction is required.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4, 6, 21 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Mizutani et al. (J. Biol. Chem. Vol.275 no.13).

Mizutani et al. teach the nucleic acids encoded by SEQ ID NO:3 and SEQ ID NO:4. See Accession Number: AB035725. Moreover, Mizutani et al. teach the expression of SYNCRIP in cells by subcloning the sequences of SYNCRIP, of which SEQ ID NO:3 is an isoform, into a plasmid in order to produce a vector construct.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6, 21 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. .

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[emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Claim 4 is drawn to a nucleic acid encoding a protein as shown in SEQ IDNO:4 having from one to ten amino acids deleted, substituted or added within the region of position 1 to 100 and retains RNA binding activity. These are genus claims that encompass a wide array of molecules. The specification does not disclose how the structures of this myriad of sequences relate to RNA binding activity. The specification does not disclose what substitutions, deletions or addition can be tolerated and where within the first 100 amino acids these changes can be tolerated. It is well known in the art that a change in a single amino acid in the primary structure of a sequence can alter the secondary structure such that the claimed activity is eliminated or altered. Thus, the specification does not describe the complete structure of a representative number of species to describe the invention claimed. The specification also fails to describe a representative number of species in terms of partial structure and relevant identifying characteristics. Absent such teachings and guidance as to the structure-function relationship of these molecules, the specification does not describe the claimed recombinant

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DNA molecules in such full, clear, concise and exact terms so as to indicate that Applicant had possession of these molecules at the time of filing of the present application.

In claim 6, Applicant also claims a DNA which hybridizes to a DNA comprising a nucleotide sequence spanning from position 154-1836 of SEQ ID NO:3 having RNA binding activity. The present claim embraces nucleic acid sequences which hybridize to fragments of positions 154-1836 of SEQ ID NO:3 as well as the full length of positions 154-1836 of SEQ ID NO:3. For reasons similar to those stated above, Applicant has not described which regions or consensus sequences are required from positions 154-1836 of SEQ ID NO:3 to maintain RNA binding activity. Thus, the specification fails to describe a representative number of species in terms of partial structure and relevant identifying characteristics. Moreover, nucleic acid hybridization does not guarantee molecules that retain RNA binding activity. No structure function relationship has been taught relating the DNA, which hybridizes to the claimed sequence and motifs or consensus sequences required for RNA binding activity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
May 1, 2003



**JAMES KETTER
PRIMARY EXAMINER**